

REMARKS

I. Status of the Application

Claims 27 – 45 are pending in the application. Applicants gratefully acknowledge the Examiner's withdrawal of the rejection of claims 27 and 28 as being unpatentable over Nonami et al. (U.S. Patent No. 5,125,971). Claims 27-33 and 36-38 stand rejected under 35 U.S.C. § 102(e) as anticipated by Leitao (U.S. Patent No. 6,069,295). Claims 34 -35 and 44 – 45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leitao. Claims 27, 28, and 32 – 36 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Li (U.S. Patent No. 6,139,585).

Applicants respectfully request reconsideration of the application in light of the foregoing arguments.

II. Claims 27-33 and 36-43 Are Novel over Leitao and Claims 34, 35, 44, and 45 Are Nonobvious over Leitao

At page 2, paragraph 1 of the present Office Action, claims 27 – 33 and 36 – 43 stand rejected under 35 US.C. § 102(e) as being anticipated by Leitao (US. Patent No. 6,069,295) in consideration of Applicants' own specification. At page 2, paragraph 2 of the present Office Action, claims 34, 35, 44, and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Leitao. The Examiner maintains that although Leitao does not explicitly teach the claimed bond strength between the coating and the implant of between 40 to 65 MPa, the Examiner assumes that the device of Leitao would necessarily have the same bond strength as the claimed bond strength because Leitao uses the same ions as Applicants. The Examiner improperly relies on Applicants' own specification to support this position.

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In the prior office action response, Applicants have specifically refuted the Examiner's inherency position with record evidence supporting that, in fact, coatings having the same ion constituents can have widely differing bond strengths. In view of this record evidence, the Examiner cannot maintain an inherency position to support the anticipation rejection. Now, the Examiner has cited Applicants' own specification and claims as evidence of the inherent bond strength of Leitao. Applicants respectfully traverse this rejection.

MPEP states that "when a reference is silent about the asserted characteristics, such gap in the reference may be filled with recourse to extrinsic evidence... [which] **must make clear** that the missing descriptive matter is **necessarily present** in the thing described in the reference" (MPEP § 2131.01 part III, emphasis added). The Examiner has asserted that the claimed bond strength of the coating is inherently disclosed in Leitao simply because Leitao discloses the same ion constituents as Applicants'. Applicants, however, have provided the Examiner with record evidence that one of skill in the art knowing only the ion constituents without knowing the method of forming a coating using the ion constituents would not be able to predict with certainty what the bond strength of the coating to the implant would be.

The implant of Kokubo et al. formed by soaking a substrate in an aqueous solution containing **calcium, phosphate and magnesium** ions just like Leitao, has a maximum bond strength of 11 MPa, which is much lower than Applicants' claimed range. Based on the coating of Kokubo et al. which comprises magnesium, calcium and phosphate and a maximum bond strength of 11 MPa, the Examiner **cannot conclude** that the coating of Leitao, which also comprises magnesium, calcium and phosphate, **necessarily has** a bond strength of 40 to 65 MPa, as required to anticipate Applicants' claimed subject matter. Thus, Leitao fails to teach all of Applicants' claim limitations.

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It is black letter law that the Examiner simply cannot rely on the Applicants' own specification to support a rejection. Leitao reports no adhesion strengths. Instead, akin to an obviousness rejection, the Examiner is attempting to cure the deficiency of Leitao by citing the Applicants' own specification and claims as evidence that the bond strength of the implants taught by Leitao is *necessarily* between 40 to 65 MPa. In effect, the Examiner is modifying Leitao which teaches no bond strength with the Applicants' claimed bond strength range to arrive at all of Applicants' claim limitations. The Examiner simply cannot bootstrap an obviousness determination based on Applicants' own specification. See *In re Pleuddemann*, 910 F.2d 823, 828 (Fed. Cir. 1990) in which the Federal Circuit held that it was legal error to use “[an inventor's patent] specification teaching as though it were prior art in order to make claims to methods appear to be obvious.” See also *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985) where the Federal Circuit held it to be error to reconstruct a patentee's claimed invention from the prior art by using the patentee's claims as a “blueprint.” Further, *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989) states that “a retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination. It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.”

Leitao fails to teach a coated implant comprising a coating having an *average bond strength* to the implant *of between 40 to 65 MPa*. For the reasons set forth above regarding the citation of Applicants' own specification and claims, Applicants submit that no reference of record has been identified which cures the deficiency of Leitao. Thus, Applicants respectfully submit that the Examiner cannot base an obviousness rejection upon an inherent bond strength that is unknown (i.e.,

not taught by the reference) and not supported in the present rejection by a secondary reference. See MPEP 2131.01 and *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989) (“Obviousness cannot be predicated on what is unknown.”).

Thus, Leitao fails to teach all of Applicants’ claim limitations. Accordingly, Applicants respectfully request that the Examiner withdraw the anticipation and obviousness rejection.

III. Claims 27, 28 and 32-36 Are Nonobvious over Li

At page 2, paragraph 3 of the present Office Action, claims 27, 28 and 32-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Li (U.S. Patent No. 6,139,585). The Examiner maintains that Li teaches a coated implant wherein the coating comprises calcium ions, phosphate ions, magnesium ions and carbonate ions, and that the implant substrate may be metal, ceramic, or polymer (Office Action dated May 22, 2001). The Examiner also maintains that Li teaches that the adhesion strength of the coating to a polished substrate is believed to be in excess of 30 MPa, and that the range of 30 MPa overlaps the range claimed by Applicants. The Examiner maintains that overlapping ranges are *prima facie* evidence of obviousness and that it would have been obvious to one of skill in the art to have selected the portion of Li’s range that corresponds to the claimed range. The Examiner continues to maintain that Li teaches the use of carbonated calcium phosphate and a coating thickness of 0.005 to 50 microns, and that the second coating taught by Applicants in claim 36 differs from Li only in requiring two layers whereas Li teaches one layer, and concludes that it is well-settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. The Examiner stated that Li inherently specifically requires the bond strength of Applicants’.

Applicants respectfully traverse the rejection and incorporate by reference herein the basis for Applicants' prior traversals of this rejection. Li states that "the adhesion strength of the coating to a polished substrate *is believed to be in excess of 30 Mpa.*" Li's statement is guesswork. Li provides no evidence or test data to support the guesswork. The Examiner is not allowed to ascribe teachings to Li that are not supported by evidence or that would not be understood by one skilled in the art.

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As stated above, Applicants have provided record evidence in Kokubo et al. supporting that, in fact, coatings having the same ion constituents can have widely differing bond strengths. Li's bond strength may be less than or equal to 30 Mpa. The Examiner cannot base an obviousness determination on what is unknown. *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989) ("Obviousness cannot be predicated on what is unknown.").

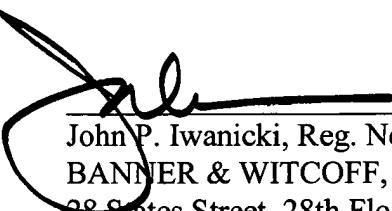
Also, the Federal Circuit has ruled that in a determination of obviousness, "[t]he prior art must be enabling." *Rockwell International Corp. v. United States*, 47 U.S.P.Q.2d 1027, 1032 (Fed. Cir. 1998). Applicants respectfully submit that Li cannot enable Applicants' claimed bond strength because Li is guessing at what its own bond strength is. Li simply cannot enable the unknown. Therefore, Li alone cannot support an obviousness determination.

IV. CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600.

Respectfully submitted,

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